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| APPLICATION NO.                | FILING DATE                                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--------------------------------|---|----------------------|-------------------------|------------------|
| 10/796,782                     | 03/09/2004                                  | George J. Brewer     | 4100.001099             | 1675             |
| 4743                           | 7590 09/07/2006                             |                      | EXAMINER                |                  |
| MARSHALL, GERSTEIN & BORUN LLP |   |                      | MAIER, LEIGH C          |                  |
|                                | 3 S. WACKER DRIVE, SUITE 6300<br>EARS TOWER |                      | ART UNIT                | PAPER NUMBER     |
| CHICAGO,                       | IL 60606                                    |                      | 1623                    |                  |
|                                |   |                      | DATE MAILED: 09/07/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Application No.   | Applicant(s)   |  |  |  |
|---|--|---|--|--|--|--|
| Office Action Summary   |  | 10/796,782  | BREWER ET AL.  |  |  |  |
|   |  | Examiner  | Art Unit   |  |  |  |
|   |  | Leigh C. Maier  | 1623   |  |  |  |
|   | The MAILING DATE of this communication app   | pears on the cover sheet with the c   | orrespondence address  |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,   |  |   |  |  |  |  |
| WHIC<br>- Exter<br>after<br>- If NC<br>- Failu<br>Any   | CHEVER IS LONGER, FROM THE MAILING D nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION (36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status  |  |   |  |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on 22 J   | une 2006.   |  |  |  |  |
| 2a) <u></u> □   | This action is <b>FINAL</b> . 2b)⊠ This  | action is non-final.  |  |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |  |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |
| Dispositi   | on of Claims   |   |  |  |  |  |
| 4)⊠ Claim(s) <u>44,81-90,92-98,102-107 and 123</u> is/are pending in the application.   |  |   |  |  |  |  |
| •   | 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |   |  |  |  |  |
| 6)⊠   | 6)⊠ Claim(s) <u>44,81-90,92-98,102-107 and 123</u> is/are rejected.  |   |  |  |  |  |
| •   | Claim(s) is/are objected to.   |   |  |  |  |  |
| 8)[_]   | Claim(s) are subject to restriction and/o  | or election requirement.  |  |  |  |  |
| Applicati   | on Papers  |   |  |  |  |  |
| 9)  | The specification is objected to by the Examine  | er.   |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |  |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                  |  |   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |   |  |  |  |  |
| Priority u  | ınder 35 U.S.C. § 119  |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:                              |  |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |  |   |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received. |  |   |  |  |  |  |
|   | ee the attached detailed Office action for a list  | of the certified copies not receive   | u.   |  |  |  |
| Attachmen   | t(s)   |   |  |  |  |  |
|   | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PTO-948)   | 4) Interview Summary Paper No(s)/Mail Da  |  |  |  |  |
| 3) 🛛 Inform   | e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date 6/22/06.  | 5) Notice of Informal P 6) Other:   |  |  |  |  |

#### **DETAILED ACTION**

# Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 22, 2006 has been entered.

Claims 80, 91, 99-101 and 108-122 are canceled. Claims 44, 81-83, 86, 87 and 93 have been amended. Claim 123 is newly added. Claims 44, 81-90, 92-98, 102-107 and 123 are pending. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration of Dr. Mazar, filed under 37 CFR 1.132, is acknowledged and addressed below.

### Claim Rejections - 35 USC § 112

Claims 44, 81-90, 92-98, 102-107 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as set forth in previous Office actions. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicant's submission filed June 22, 2006 have been fully considered but they are not persuasive. In response to the rejection of record, Applicant has submitted a declaration by Dr. Andrew Mazar that purport to demonstrate that thiomolybdate compounds are enabled for the treatment of ocular neovascularization, rather than limited to the prevention.

The examiner agrees that Exhibit 2 demonstrates prevention but does not agree that the data, as presented in Exhibit 3, necessarily support a "trend towards regression of CNV." The fact that there is less CNV with the TM compounds than the control could be entirely due to inhibition of further CNV after the 14-day non-treatment period.

Exhibit 5 does appear to support regression. However, Applicant is reminded that the method must be enabled by the specification. The specification states that the therapeutic dosages for an average human male would be between 0.3 mg/kg and 3.0 mg/kg. See page 10, 1<sup>st</sup> full paragraph. However, the dosage used in the experiments from which the exhibit 5 data were taken is 50 mg/kg, an order of magnitude greater than the dosages contemplated in the specification. The examiner does not find the specification to be enabling when it would appear that it would require one of ordinary skill to make the leap from the dosages recommended in the specification to one over ten times greater than said dosages in order to see positive results.

Claims 44, 81-90, 92-98, 102-107 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

The amendment to claim 44 adds a limitation requiring a "loading dosage of greater than 200 mg daily." The examiner finds a discussion of loading dosages at the paragraph bridging pp 55-6. The specification discloses the range "greater than about 200 mg or so *up to the maximum dosages described herein.*" (Emphasis added.) The examiner does not find support for the range "greater than 200 mg."

# Double Patenting

Claims 44, 83-85, 104, 106, 107, and 116-122 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-48 and 57 of U.S. Patent No. 6,703,050, as set forth in the previous Office action.

Claim 44 has added the limitation requiring a loading dosage of greater than 200 mg. In carrying out the invention set forth in the claims, one of ordinary skill would look to the written description of the invention, including dosages outlined. Such loading dosages are disclosed at col 35, lines 10-35. It would have been obvious to one of ordinary skill to select a dosage set forth in the written description and arrive at the instant invention.

Applicant has previously indicated a willingness to file a terminal disclaimer if necessary upon a finding of allowable subject matter.

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## Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://www.uspto.gov. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Primary Examiner

September 5, 2006